K033863

AUG 2 2 2005

510(k) PREMARKET SUMMARY

General Information:

1. Original Date Submitted: November 10, 2003

2. Submitted By:

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Boise, ID 83705
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Contact Person: Frank Fosella, Jr.

3. Device Trade Name: OX-GEN Rigid O_2 Generation System, Model 5-OX-03
Common Name: Portable Oxygen Generator
Classification Name: Portable Oxygen Generator

4. Legal to Market
Predicate Device:

Jet Research Center, Model 415 Oxygen Canister and Dispenser, Model 3445-c.
510(k): K780020

Canogen International LTD., Model 615 Portable Oxygen Generator.
510 (k): K982243

5. Device Description:

The OX-GEN Rigid O_2 Generation System, Model 5-OX-03 is found to be substantially equivalent in that it produces a minimum of 6 liters per minute of 99% pure oxygen for a 15 minute interval, by means of a chemical reaction. The OX-GEN Rigid O_2 Generation System is composed of three self-contained chambers that when opened are activated and begin to generate instant, non-pressurized oxygen. The second part of the device consists of the plastic tubing, an inline filter and an oxygen mask, which are attached to the outlet of the oxygen generator.

6. Indications for Use:

The OX-GEN Rigid O_2 Generation System, Model 5-OX-03 is intended to produce instant, non-pressurized oxygen for emergency uses.

TECHNOLOGICAL COMPARISON

The OX-GEN Rigid O_2 Generation System, the Jet Research Center Model 415 and the Canogen Portable Oxygen Generator Model 615 are all designed to generate oxygen as a result of a chemical reaction. All three devices are comprised of a kit containing the reaction container, pre-measured chemicals and accessories to provide oxygen for emergency use.

Jet Research Center Model 415 and the Canogen Portable Oxygen Generator Model 615 use a hard plastic multi-chambered reaction container. The container provides several functions. First, it serves as the packaging for the Jet Research Center Model 415 and the Canogen Portable Oxygen Generator Model 615 kits and contains the pre-measured chemicals and accessories. Second, when oxygen is to be created, it serves as the container for mixing the pre-measured chemicals. Third, the container serves as the chamber that houses the chemically created oxygen that is then delivered through the accessories. Finally, the reaction container can be reused.

The Jet Research Center Model 415 and the Canogen Portable Oxygen Generator Model 615 requires combining the chemicals in a sequential process to create oxygen which takes in excess of seven minutes. The initiation of the process is a manual action performed by the user. After mixing the chemicals, the oxygen creation begins immediately.

The OX-GEN Rigid O_2 Generation System Model 5-OX-03 is a rigid three chambered container with the pre-measured chemicals that are needed for the generation of oxygen already in place in the appropriate chambers. The top chamber contains water for cooling and cleaning the oxygen that is produced. The middle chamber contains the dilute hydrogen peroxide. The top and middle chambers are connected by a rotary valve with o-rings, Valve #3, to create a seal between the chambers and the outside of the device. The bottom chamber contains the granular sodium percarbonate. The middle and bottom chambers are connected with a flat valve, Valve #1, which is opened or closed by a rotary cam shaft. The cam shaft has o-rings to seal it from the outside of the device. The flat valve has several o-rings for sealing purposes as well as an area for catalyst storage. The catalysts can also be contained within a special chamber-type valve, Valve #2, located in the bottom chamber area. The three valves are opened in a numbered sequence to allow the chemicals and catalyst to mix and react. The reaction that occurs creates the release of oxygen. The oxygen exits the device by first entering the now empty middle chamber where any foam or bubbles break up. It then enters the top chamber where it bubbles through the water for cooling and scrubbing (cleaning) for removal of any possible carryover of the react chemicals. It leaves the device through the top nipple and is conveyed by the Salter Labs Three-channel Oxygen Safety Tubing to the inline moisture trap/activated carbon filter and then on through more Three-channel tubing to the Slater Labs Oxygen Mask.

The generation of oxygen begins immediately when the chemicals mix and increases to a flow rate of at least 6 liters per minute within 1 to 1 ½ minutes. The flow rate of 6 liters per minute or more is maintained for at least 15 minutes and then decreases to zero over the next 10 minutes.

The maximum temperature of the oxygen measured at the mask is 33°C. The water chamber on top of the device cools and cleans the oxygen after it is produced by the exothermic reaction of generating chemicals.

The chemical reaction that occurs within the OX-GEN Rigid O_2 Generation System Model 5-OX-03 is as follows:

The reaction can be considered a two phase reaction; first the liquid hydrogen peroxide reacts with the catalysts to produce oxygen and water and then that water and the sodium percarbonate and catalysts react to produce additional oxygen.

The chemical formulas are as follows:

$$2\ H_2O_2 \xrightarrow[Pt]{MnO_2} 2\ H_2O + O_2$$

$$2(2Na_2CO_3 \cdot 3H_2O_2) \xrightarrow[Water]{MnO_2 + Pt} 4\ Na_2CO_3 + 6\ H_2O + 3\ O_2$$

The chemicals used in the OX-GEN Rigid O_2 Generation System Model 5-OX-03 consist of water in the top chamber, 6.0% hydrogen peroxide in the middle chamber, manganese dioxide and platinum powder in the flat valve cavity and the chamber-type valve, and sodium percarbonate in the bottom chamber. The catalysts promote the decomposition of the liquid hydrogen peroxide to water and oxygen and in turn the sodium percarbonate decomposes to sodium carbonate, water, and oxygen. These reactions are exothermic and heat is therefore generated. By the completion of the oxygen generating reaction, the temperature of the reactant products reaches 89 to 90°C.

After the oxygen generating reaction is complete, usually about 27 to 28 minutes, Valve #3 should be closed and the red cap should be replaced on the outlet nipple to seal the device closed. All components of the OX-GEN Rigid O_2 Generation System Model 5-OX-03 are designed for single use only and need to be returned to the manufacturer for any recharging. In the event that the unit gets disposed of the contents are not a toxic hazard. They are water, sodium carbonate (soda ash) which is a naturally occurring salt, and the manganese dioxide and platinum which occur naturally in the environment as minerals.

If any of the unreacted chemicals get spilled or leak from the OX-GEN Rigid O_2 Generation System Model 5-OX-03 they will be either water, a weak hydrogen peroxide solution, granulated or liquefied sodium percarbonate, and the two catalysts manganese dioxide and platinum. The hydrogen peroxide should be rinsed down with water. The granulated or liquefied sodium percarbonate is the same compound as that found in common powdered oxygen bleaching products that are used for household, laundry, carpet, and deck cleaning chores. It should be rinsed down with water. The two catalysts are present in very small amounts and can be washed down along with the other chemicals without undue concern. If any of these chemicals come in contact with the skin or eyes,

rinse the affected area with cool water. If irritation persists medical advice should be sought.

The OX-GEN Rigid O_2 Generation System, the Jet Research Center Model 415 and the Canogen Portable Oxygen Generator Model 615 use different pre-measured chemicals. The results of combining these chemicals are all the same. They all generate emergency oxygen.

SUBSTANTIAL EQUIVALENCE DATA SUMMARY

The OX-GEN Rigid O_2 Generation System Model 5-OX-03, the Jet Research Center Model 415, and the Canogen Portable Oxygen Generator Model 615 are substantially equivalent in that they are designed to generate oxygen as a result of a chemical reaction. All three devices are provided in kit form with the necessary containers, chemicals, and accessories to provide oxygen for emergency use. The Jet Research Center Model 415 and Canogen Model 615 use cartridges containing chemicals inserted into the reaction vessel which contains the reaction and ports the gas to the face mask tubing. While substantially equivalent, the OX-GEN Rigid O_2 Generation System Model 5-OX-03 uses a three chamber container with valves that connect the chambers. The valves are opened enabling the chemicals to mix, react, and port the oxygen to the face mask tubing.

All devices are substantially equivalent to one another in that they are intended to be emergency use devices. The targeted population is also equivalent by directing marketing to healthy individuals in emergency situations"

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2005

Mr. Frank Fosella
Ox-Gen Incorporated
P.O. Box 5867
Boise, Idaho 83702

Re: K033863
Trade/Device Name: OX-GEN, Incorporated
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable oxygen generator
Regulatory Class: II
Product Code: CAW
Dated: June 17, 2005
Received: June 20, 2005

Dear Mr. Fosella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for use

510(k) Number (if known): K033863

Device Name: OX-GEN Rigid O2 Generation System
Model 5-OX-03

Indication for use:

The OX-GEN Rigid O2 Generation System, Model 5-OX-03 is intended to produce oxygen for emergency use.

Prescription Use _____ AND / OR Over-The-Counter Use **X**
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033863